IN THE UNITED STATES DISTRICT COURT
FOR THE SOUTHERN DISTRICT OF NEW YORK

REGENERON PHARMACEUTICALS, INC.,

Plaintiff,

v.

UNITED STATES DEPARTMENT OF HEALTH AND HUMAN SERVICES, *et al.*,

Defendants.

Case No. 7:20-CV-10488-KMK

DEFENDANTS' OPPOSITION TO PLAINTIFF'S MOTION FOR TEMPORARY RESTRAINING ORDER AND PRELIMINARY INJUNCTIVE RELIEF

TABLE OF CONTENTS

TABLE OF AUTHORITIES

CASES

STATUTES

REGULATIONS

UNITED STATES CONSTITUTION

OTHER AUTHORITIES

INTRODUCTION

Medicare Part B costs are increasing at a financially unsustainable rate, particularly with respect to certain drugs, greatly impacting the public fisc and the wallets of vulnerable seniors. The financial impact on seniors has been compounded by the COVID-19 pandemic, at a time when chronic-disease management is most important, giving rise to a particularly urgent need to provide relief in light of the new wave of COVID-19 infections sweeping the nation. At the same time, the United States pays significantly more for prescription drugs than all other developed countries, resulting in an unfair burden on Medicare beneficiaries and on American taxpayers. In response, the Centers for Medicare & Medicaid Services ("CMS") exercised its statutory authority to promulgate a cost-saving reimbursement model for approximately 50 Medicare Part B drugs, representing the highest proportion of overall Part B spending, based on the costs of those drugs in other countries, titled the Most Favored Nation Model ("the Rule"). The Rule is predicted to result in a savings of $85.5 billion in Medicare Part B spending, and $28.5 billion for Medicare beneficiaries. Most Favored Nation (MFN) Model, 85 Fed. Reg. 76,180, 76,181 (Nov. 27, 2020).

Plaintiff Regeneron Pharmaceuticals seeks a temporary restraining order against the Rule on a number of procedural and substantive grounds. As a threshold matter, the court lacks jurisdiction to consider Plaintiff's claims for two reasons. *First*, Plaintiff has not presented a claim for reimbursement to the Secretary. The Medicare statute bars the court from considering any claim arising under the statute that is not first presented to the Secretary for reimbursement. *Second*, the Medicare statute explicitly bars judicial review of the selection and design of Medicare models such as the one challenged here.

In any event, Plaintiff's substantive claims are without merit. CMS complied with all relevant procedures in promulgating the Rule, and the Rule is a valid and constitutional exercise of CMS's statutory authority. *Finally*, Plaintiff is not irreparably harmed, and thus has not satisfied the demanding standard for issuance of a temporary restraining order. For these reasons, the Court should deny Plaintiff's motion for a temporary restraining order and preliminary injunction.

BACKGROUND

I. The Center for Medicare and Medicaid Innovation

When Congress enacted the Patient Protection and Affordable Care Act of 2010 ("ACA"), it also created the Center for Medicare and Medicaid Innovation ("the Center"). The Center exists to "test innovative payment and service delivery models" with the goal of "reduc[ing] program expenditures" while maintaining, or even improving, a high standard for "quality of care." 42 U.S.C. § 1315a(a)(1). The Secretary has wide discretion to select models for testing. In selecting a model for Phase I testing, the Secretary of Health and Human Services need only determine that the model "addresses a defined population" for which there are either: (1) "deficits in care leading to poor clinical outcomes;" or (2) "potentially avoidable expenditures." *Id.* § 1315a(b)(2)(A). Congress directed the Secretary to "focus" on "models expected to reduce program costs" while also "preserving or enhancing the quality of care." *Id.* The statute provides a list of illustrative examples, such as, "[p]romoting broad payment and practice reform in primary care," *id.* § 1315a(b)(2)(B)(i). And though the Secretary "may elect to limit testing of a model to certain geographic areas," there is no requirement to do so. *Id.* § 1315a(a)(5).

Congress also directed the Secretary to "terminate or modify" the model after Phase I testing has begun unless it is expected to: (1) "improve the quality of care . . . without increasing spending;" (2) "reduce spending . . . without reducing the quality of care;" or (3) "improve the quality of care and reduce spending." *Id.* § 1315a(b)(3)(B). The Secretary is also required to evaluate each model tested and make the results of the evaluation available to the public. *Id.* § 1315a(b)(4)(A)-(B). After taking into account the evaluation of the Phase I test, the Secretary "may, through rulemaking, expand . . . the duration and the scope of a model" to Phase II if the Secretary determines that the goals of the statute are satisfied. *Id.* § 1315a(c).

In recognizing the difficulties in creating innovative models, Congress sought to give the Center significant flexibility to do so. Congress gave the Secretary authority to waive otherwise applicable statutory or regulatory requirements "for the purposes of carrying out this section with respect to testing models." *Id.* § 1315a(d)(1). Congress also barred judicial review of the Secretary's

decisions, stating that "[t]here shall be no administrative or judicial review" of, among other things: (1) "the selection of models for testing or expansion under this section;" (2) "the selection of organizations, sites, or participants to test those models selected;" and (3) "the elements, parameters, scope, and duration of such models for testing or dissemination." *Id.* § 1315a(d)(2).

II. The Most Favored Nation Model Interim Final Rule

On November 27, 2020, CMS issued the interim final rule, "Most Favored Nation (MFN) Model" Rule. The Rule responds to "[i]ncreases in drug prices" that have been "accelerating at a rate that significantly outpaces the growth in spending on other Medicare Part B services" and the disparity that these prices in the U.S. "far exceed prices in other countries." 85 Fed. Reg. 76,180.[1]

Currently, the price of Medicare Part B drugs is set using the statutory methodology set forth in 42 U.S.C. § 1395w-3a. Most of the time, this "means payment is based on the Average Sales Price ("ASP") plus a statutorily mandated 6 percent add-on." 85 Fed. Reg. 76,180. Because the ASP "is calculated using only the prices that manufacturers charge to certain U.S.-based purchasers," CMS found that "the Medicare program does not get the benefit of the substantial discounts provided in other countries." *Id.* at 76,180–81. And because the dollar amount of the add-on is higher for drugs with higher ASPs, CMS concluded that "ASP-based payments may encourage the use of more expensive drugs." *Id.* at 76,181. This also translates to higher costs for beneficiaries, as "beneficiaries' cost-sharing is generally 20 percent of the Medicare-allowed amount." *Id.* at 76,182.

To address these concerns, CMS used its authority under § 1315a to create the Most Favored Nation Model ("MFN Model"). The MFN Model will test the reduction in Medicare Part B spending by the Government and beneficiaries in two ways: (1) by "[c]alculat[ing] the payment amount for MFN Model drugs based on a price that reflects the lowest per capita Gross Domestic Product-adjusted . . . price of any non-U.S. member country of the Organisation for Economic Co-operation and Development . . . with a [Gross Domestic Product] that is at least sixty percent of the U.S. [Gross

[1] Medicare is a federal health insurance program for the elderly and disabled, *see* 42 U.S.C. § 1395 *et seq.*, which is administered on behalf of the Secretary by CMS. Medicare Part B "is an optional supplemental insurance program that pays for medical items and services" including certain drug coverage. *Ne. Hosp. Corp. v. Sebelius*, 657 F.3d 1, 2 (D.C. Cir. 2011).

Domestic Product] per capita"; and (2) by "[m]ak[ing] an alternative add-on payment for MFN Model drugs that will remove or reduce the financial incentive to prescribe higher-cost drugs more frequently." *Id.* at 76,181. CMS estimates that this model will result in more than $80 billion in savings for the Government and $28.5 billion in savings for Medicare beneficiaries over a seven-year period. *Id.*

The MFN Model will include approximately 50 drugs that have the "highest aggregated Medicare Part B total allowed charges in the baseline period." *Id.* at 76,189. CMS determined that, "[c]ompared to beginning with a smaller number of drugs and phasing in additional drugs in each subsequent performance year, beginning with 50 Medicare Part B drugs simplifies the model design and reduces complexity for MFN participants." *Id.* CMS defined the population for this Model as the beneficiaries who receive one of these drugs from a MFN Model participant, reasoning that this "allows the MFN Model payment to apply to a broad set of conditions, drugs, medical specialties, clinical settings, and localities rather than having MFN Model payment focused on a particular clinical presentation, course of treatment, or single type of care setting." *Id.* at 76,183.

The MFN Model requires mandatory participation because "mandatory participation can enhance generalizability of model results, as mandatory model participants may be more broadly representative of all entity types that could be affected by a model." *Id.* at 76,187. CMS explained that it was important for the MFN Model to be tested on a nationwide scale for four reasons: (1) to avoid "administrative burden" on providers with locations across the country; (2) to "eliminate the potential" for multi-location providers to influence where beneficiaries seek treatment; (3) to "maintain[] continuity with current treatment patterns;" and (4) to "allow[] all eligible beneficiaries" to "benefit from the cost-sharing reductions." *Id.* at 76,187–88.

Though CMS is testing the MFN Model over seven years, it is phasing in the new pricing structure 25 percent per year over the first three years, only reaching 100 percent of the new price during the last four years of the model. *Id.* at 76,205. This phase-in approach allows time for participants "to adjust to the model payment amounts and processes." *Id.* at 76,204. Thus, in the first year, participants will be reimbursed 75% of the ASP, and only 25% of the MFN Price. *Id.* at 76,205.

CMS found good cause to waive notice and comment requirements "because of the particularly acute need for affordable Medicare Part B drugs now, in the midst of the COVID-19 pandemic." *Id.* at 76,249. CMS noted that the high costs of drugs in the U.S. has "serious economic and health consequences for beneficiaries in need," causing them to "divert scarce resources to pharmaceutical treatments and away from other needs" or even to "skip doses of their medications" or "abandon treatment." *Id.* Particularly with more than 25 million Medicare beneficiaries living at or below 200 percent of the Federal Poverty Line, CMS concluded that high drug prices could result in "poor clinical outcomes for chronic disease management." *Id.*

CMS explained that the COVID-19 pandemic has exacerbated these concerns. As CMS noted in the Rule, the unemployment rate and number of unemployed persons remain at nearly twice the pre-pandemic levels. *Id.* The pandemic has "also led to an increase in food prices, straining budgets for many of America's seniors, particularly those who live on fixed incomes, such as the 6 million Medicare fee-for-service beneficiaries without supplemental coverage and over 12 million beneficiaries dually eligible for Medicare and Medicaid." *Id.* Accordingly, CMS determined that "the burdens placed on America's seniors and other Medicare Part B beneficiaries" have "given rise to an urgent need for swift action to reduce drug prices." *Id.* In particular, CMS noted that, after "some positive economic and employment trends since the initial peak in April," there is a "new surge in COVID-19 cases that may lead to additional hardship and requires immediate action." *Id.* CMS expects that the implementation of the Rule will "provide immediate relief to Medicare beneficiaries through reduced copays for MFN drugs due to lower drug payments and no beneficiary cost-sharing on the alternative add-on payment." *Id.* For the same reasons, CMS also found good cause to waive the requirements for a delay in effective date under the APA and 42 U.S.C. § 1871(e)(1)(B). *Id.*

III. This Litigation

Plaintiff filed its Complaint on December 11, 2020, raising eight claims challenging the Rule. *See* Complaint, ECF No. 1 ("Compl."). First, Plaintiff alleges that Defendants issued the Rule in violation of the Administrative Procedure Act's ("APA") notice and comment procedures under 5 U.S.C. § 553 and the notice and comment provisions of the Medicare statute. *Id.* ¶¶ 71–80. Next,

Plaintiff alleges that the Rule is contrary to law and *ultra vires* because it exceeds Defendants' statutory authority under 42 U.S.C. § 1315a. *Id.* ¶¶ 81–85. In addition, Plaintiff alleges that the Rule is arbitrary and capricious. *Id.* ¶¶ 86–90. Plaintiff also alleges that the Rule was issued in violation of the Constitution's Presentment Clause, constitutes an unlawful delegation of authority to the Executive Branch, and violates the First Amendment, the Foreign Commerce Clause, the Fifth Amendment's Due Process Clause, and the Takings Clause. *Id.* ¶¶ 91–110. In addition to declaratory relief, Plaintiff asks the Court to set aside and vacate the Rule, and to "enjoin implementation and enforcement of the MFN Rule." *Id.*, Prayer for Relief.

On the same day as Plaintiff filed its Complaint, Plaintiff also moved for a preliminary injunction and temporary restraining order. Mem. of Law in Supp. for a Prelim. Inj., ECF No. 14 ("Pl.'s Mot."). The court *sua sponte* issued an order to show cause as to why an order should not be issued preliminarily enjoining or temporarily restraining Defendants from implementing and enforcing the Rule. ECF. No. 20. Defendants were ordered to respond on or before December 16, 2020. *Id.*

LEGAL STANDARD

"[A] preliminary injunction is an extraordinary and drastic remedy, one that should not be granted unless the movant, by a *clear showing*, carries the burden of persuasion." *Sussman v. Crawford*, 488 F.3d 136, 139–40 (2d Cir. 2007) (quoting *Mazurek v. Armstrong*, 520 U.S. 968, 972 (1997)). "[A] plaintiff seeking a preliminary injunction must establish that he is likely to succeed on the merits, that he is likely to suffer irreparable harm in the absence of preliminary relief, that the balance of equities tips in his favor, and that an injunction is in the public interest." *Winter v. Nat. Res. Def. Council, Inc.*, 555 U.S. 7, 20 (2008); *see also New York v. U.S. Dep't of Homeland Security*, 969 F.3d 42, 58 (2d Cir. 2020) (applying the "preliminary injunction framework laid out in *Winter*"), *petition for cert. filed*, No. 20-449 (U.S. Oct. 8, 2020). "Where, as here, the government is a party to the suit," the balance of hardships and the public interest merge. *Nken v. Holder*, 556 U.S. 418, 435 (2009); *see also New York,* 969 F.3d at 58–59. "The standard[s] for granting a temporary restraining order and a preliminary injunction

pursuant to Rule 65 of the Federal Rules of [Civil] Procedure are identical." *Sterling v. Deutsche Bank Nat'l Trust Co.*, 368 F. Supp. 3d 723, 726–27 (S.D.N.Y. 2019) (quoting *Spencer Trask Software & Info. Servs., LLC v. RPost Int'l Ltd.*, 190 F. Supp. 2d 577, 580 (S.D.N.Y. 2002)).

ARGUMENT

I. PLAINTIFF IS UNLIKELY TO SUCCEED ON THE MERITS OF ITS CLAIMS.

A. Plaintiff's Claims are Barred from Judicial Review.

i. The Medicare Statute Withdraws Subject Matter Jurisdiction Over Plaintiff's Claims Because it Failed to Present a Claim for Reimbursement.

District courts may exercise jurisdiction over claims arising under the Medicare statute only if the claimant obtains a "final decision" from the Secretary. 42 U.S.C. §§ 405(g), 1395ff(b); *Shalala v. Ill. Council on Long Term Care, Inc.*, 529 U.S. 1, 5, 15 (2000). Ordinarily a final decision comprises two basic components: (1) presentment of a "concrete claim for reimbursement" to HHS (and the receipt of an initial determination), *Heckler v. Ringer*, 466 U.S. 602, 622 (1984); and (2) exhaustion of administrative appeals, 42 U.S.C. § 1395ff; 42 C.F.R. § 405.904(a)(2). A party cannot waive the presentment requirement. *Ill. Council*, 529 U.S. at 15; *see also Bird v. Thompson*, 315 F. Supp. 2d 369, 374 (S.D.N.Y. 2003) (recognizing presentment requirement is "jurisdictional" and "nonwaivable"). This requirement applies to Plaintiff's procedural, statutory, and constitutional claims with equal force. *See Ringer*, 466 U.S. at 614 (holding that Secretary's "alleged failure to comply with the rulemaking requirements of the APA" was "inextricably intertwined" with their underlying claim, and thus barred from judicial review); *Three Lower Counties Community Health Servs., Inc. v. U.S. Dep't of Health & Human Servs.*, 317 F. App'x 1, 2 (D.C. Cir. 2009) ("Parties challenging Medicare rules must exhaust the agency review process regardless of whether the matter involves a direct constitutional, statutory, or regulatory challenge.") (citing *Ill. Council*, 529 U.S. at 5).

Here, Plaintiff challenges agency action taken under 42 U.S.C. § 1315a, indisputably part of the Medicare statute, and the agency action is promulgation of a model specific to Part B of the Medicare program. *See Weinberger v. Salfi*, 422 U.S. 749, 761–62 (1975) (finding that case arises under the Act when the Act "provides both the standing and the substantive basis for the present

contentions"). Yet, Plaintiff has not presented a claim for reimbursement. Nor could Plaintiff, as the MFN Model does not take effect until January 1, 2020. *See* 85 Fed. Reg. 76,181. Thus, the Court's jurisdiction is barred by 42 U.S.C. §§ 405(h), (g); *see also Fox Ins. Co. v. Sebelius*, 381 Fed. App'x. 93, 97 (2d. Cir. 2010) (affirming dismissal "[b]ecause a final agency ruling is a prerequisite to federal jurisdiction over Medicare Act claims").

That only patients and their representatives, along with healthcare providers, can submit claims for reimbursement does not mean that the non-provider plaintiff in this case may escape the jurisdictional bar. "[T]he *Illinois Council* exception is not intended to allow section 1331 federal question jurisdiction in every case where section 405(h) would prevent a particular individual or entity from seeking judicial review." *Council for Urological Interests v. Sebelius*, 668 F.3d 704, 711 (D.C. Cir. 2011). For example, in *National Athletic Trainers' Ass'n, Inc. v. U.S. Department of Health and Human Services*, the Fifth Circuit rejected an attempt by a group of athletic trainers to invoke the *Illinois Council* exception even though the trainers, "because they [were] neither beneficiaries nor providers," could not "obtain administrative review" of a new Medicare regulation. 455 F.3d 500, 504 (5th Cir. 2006). The court held that the *Illinois Council* exception was unavailable where "a third party can assert the claim." *Id.* In that case, because physicians had "sufficient incentive to challenge the rule" and could "pursue administrative review" of individual claims, the court held that it "lacked subject matter jurisdiction over [the trainers'] claim." *Id.* at 504, 507–08; *see also Sw. Pharm. Sols., Inc. v. CMS*, 718 F.3d 436, 444–46 (5th Cir. 2013); *Am. Chiropractic Ass'n, Inc. v. Leavitt*, 431 F.3d 812, 816–17 (D.C. Cir. 2005).

The relevant question, then, is not whether Plaintiff has a means to obtain review, but rather whether channeling "would . . . mean no review at all," *Ill. Council*, 529 U.S. at 17, of the contention that the Rule unlawfully sets Medicare Part B reimbursement rates. But, there *is* potentially review of that contention. Providers seeking to challenge Medicare Part B reimbursements do not face uniquely "serious practical roadblock[s] to having their claims reviewed in any capacity." *Physician Hosps. of Am. v. Sebelius*, 691 F.3d 649, 655 & n.4 (5th Cir. 2012) (citation omitted). In the Medicare Act, "[p]arties are generally required to exhaust their administrative remedies, in part because of concerns for

separation of powers . . . and the need to conserve judicial resources." *Pavano v. Shalala*, 95 F.3d 147, 150 (2d Cir. 1996). Accordingly, this Court should refrain from allowing Plaintiff to short circuit the administrative process by bypassing the mandatory presentment requirement.

ii. Congress Barred Judicial Review of Decisions Related to the Center's Discretion.

Plaintiff casts its claims in a variety of ways, but, at bottom, it challenges the "selection," "elements," "parameters," "scope," and "duration" of the MFN Model, which may not be judicially reviewed. *See* 42 U.S.C. § 1315a(d)(2). While there is undoubtedly a presumption of judicial review of administrative actions, it is just that—a presumption—which "may be overcome by clear and convincing indications, drawn from specific language, specific legislative history, and inferences of intent drawn from the statutory scheme as a whole." *Cuozzo Speed Technologies, LLC v. Lee*, 136 S. Ct. 2131, 2140 (2016) (citations omitted). Here, Congress unambiguously stated:

> "There shall be no . . . judicial review . . . of . . .," among other things: (1) "the selection of models for testing or expansion under this section;" (2) "the selection of organizations, sites, or participants to test those models selected;" and (3) "the elements, parameters, scope, and duration of such models for testing or dissemination."

42 U.S.C. § 1315a(d)(2). When, as here, "Congress provides that 'there shall be no administrative or judicial review' of specific agency actions," the "intent to bar review is clear," so the Court need only determine whether this action "falls within the preclusive scope of the statute." *DCH Reg. Med. Ctr. v. Azar*, 925 F.3d 503, 505-06 (D.C. Cir. 2019) (quoting 42 U.S.C. § 1395nn(i)(3)(I)). All of Plaintiff's claims fall within the scope of the statute because they attack the "selection" or an "element" of some aspect of the model, both of which are barred by the plain text of § 1315a(d)(2).

1. Plaintiff may not escape § 1315a(d)(2)'s judicial bar by characterizing its claims as *ultra vires*. *See* Pl.'s Mot. 20 n.19. The mere characterization of Plaintiff's claim as an attack on the agency's authority is insufficient to overcome the statutory bar. When, as here, "the statute provides us with clear and convincing evidence that Congress intended to deny" judicial review, the characterization of a claim as *ultra vires* is insufficient to confer subject matter jurisdiction. *Bd. of Governors of Fed. Reserve*

System v. MCorp, 502 U.S. 32, 44 (1991); *accord DCH Reg. Med. Ctr.*, 925 F.3d at 509 ("Following *MCorp*, there is not much room to contend that courts may disregard statutory bars on judicial review just because the underlying merits seem obvious.").

Ultra vires review is . . . only available in extraordinary circumstances. *See DCH Reg. Med. Ctr.*, 925 F.3d at 509 (noting "extremely limited scope" and "extraordinarily narrow" nature of ultra vires claims). To overcome an express statutory bar such as § 1315a(d)(2), a party must satisfy three requirements: "(i) the statutory preclusion of review is implied rather than express; (ii) there is no alternative procedure for review of the statutory claim; and (iii) the agency plainly acts in excess of its delegated powers and contrary to a specific prohibition in the statute that is clear and mandatory." *Id.* (citation omitted). Plaintiff does not satisfy the first or third requirement.

First, in barring judicial review, Congress explicitly stated that there shall be "no . . . judicial review," of the selection and elements of the Center's models. 42 U.S.C. § 1315a(d)(2). Because the "preclusion of review" is express, and not "implied" by the statute's "silence," Congress provided "clear and convincing evidence" of its intent to preclude judicial review of claims such as this, even when styled as *ultra vires* claims. *MCorp*, 502 U.S. at 44. If this court were to permit Plaintiff to attack the MFN Model simply by claiming that the Secretary's choice of the model was *ultra vires*, the court would end up "engag[ing] in the kind of case-by-case review of the reasonableness or procedural propriety of the Secretary's [decisions] that Congress intended to bar," rendering the statutory bar on review meaningless. *Fla. Health Sci. Ctr. v. Sec'y of Health and Human Servs.*, 830 F.3d 515, 522 (D.D.C. 2016); *see also Franklin Cty. Employment and Training Admin. v. Donovan*, 707 F.2d 41, 44 (2d. Cir. 1982) ("Were we to accept [the ultra vires] argument, the exhaustion requirement would be of little import since virtually every challenge to an agency's action can be clothed in the rhetoric of a 'lack of authority.'").

Regardless, Plaintiff fails to demonstrate that the agency "plainly act[ed] in excess of its delegated powers and contrary to a specific prohibition in the statute that is clear and mandatory," which is also fatal to Plaintiff's attempt to circumvent the statutory bar. *DCH Reg. Med. Ctr.*, 925 F.3d at 509. Even if the Court were to decide whether this requirement is satisfied, it "need not reach the

ultimate merits" of the agency's position. *See Long Term Care Partners LLC v. United States*, 516 F.3d 225, 234 (4th Cir. 2008). Rather, it must only answer the "more basic question of whether there is a strong and clear demonstration of a violation of a clear, specific, and mandatory statutory provision, or whether the agency's view, while perhaps not compelling beyond cavil, is nevertheless plausible." *Id.* at 235. And if the agency's position is "capable of two plausible interpretations, the Secretary's decision to adopt one interpretation over the other does not constitute a violation of a clear statutory mandate." *Id.* For the reasons explained *infra*, pages 17–20, Plaintiff cannot satisfy this requirement.

In crafting arguments related to the Secretary's purported *ultra vires* actions, Plaintiff has attempted what is "essentially a Hail Mary pass—and in court as in football, the attempt rarely succeeds." *Nyunt v. Chairman, Broad. Bd. of Governors*, 589 F.3d 445, 449 (D.C. Cir. 2009). So too here. Congress's intent to bar claims such as those Plaintiff brings is clear, and the court lacks subject matter jurisdiction over Plaintiff's statutory claims.

2. Plaintiff's constitutional claims are also included in § 1315a(d)(2)'s judicial bar. Where Congress has broadly precluded all judicial review related to the selection and scope of models under the statute, it is reasonable to include constitutional claims within the scope of the preclusive bar. Ultimately, however, the Court need not decide whether Congress intended to bar judicial review of all constitutional claims related to the Center, as Plaintiff's constitutional claims are statutory claims reinvented. *See, e.g.*, *Synopsys, Inc. v. Matal*, 280 F. Supp. 3d 823, 834 (E.D. Va. 2017) (rejecting plaintiff's "attempt to use artful pleading to circumvent" statutory bar to judicial review). Plaintiff argues that the Rule violates the Constitution's bicameralism and presentment requirement because the Rule operates as a repeal of essential portions of the Medicare Act, Pl.'s Mot. 17–18, and runs afoul of the First Amendment because of the President's statements, *id.* at 18–19. But the bicameralism and presentment argument is no more than a challenge to the Secretary's waiver of sections of the Medicare statute, which is explicitly contemplated in § 1315a(d)(1), and is explicitly barred as an "element" of the model, *id.* § 1315a(d)(2)(c). The First Amendment claim is no more than a misstatement of the decision maker, when the Secretary's selection of the model is also explicitly barred from review. When, as here, a plaintiff makes "speculative and conclusory allegations of

constitutional violations" that are "essentially characterizations" of the challenge to the underlying merits, the Court "do[es] not have jurisdiction to review such a determination." *See Hegab v. Long*, 716 F.3d 790, 791 (4th Cir. 2013).

3. Plaintiff argues that § 1315a(d)(2) does not apply to its notice and comment claim. *See* Pl.'s Mot. 20 n.19. But, in the Medicare context, courts have generally held that the purported distinction between procedural and substantive challenges is irrelevant to determining the availability of judicial review.

Most instructive is the Supreme Court's decision in *Heckler v. Ringer*, 466 U.S. 602 (1984), in which Medicare beneficiaries sought to challenge a policy of not providing reimbursement for a certain operation, including on the ground that "the Secretary violated the rulemaking requirements of the APA, 5 U.S.C. § 553, in issuing" the challenged policy. *Id.* at 610 n.7. The beneficiaries did not comply with the Medicare administrative process, but instead sought to invoke general federal-question jurisdiction under 28 U.S.C. § 1331. The Court explicitly rejected the beneficiaries' attempt to justify their claims as "procedural" in nature and outside the preclusion provision. *Ringer*, 466 U.S. at 614.

Noting that the beneficiaries included a challenge to the Secretary's "alleged failure to comply with the rulemaking requirements of the APA," the Court found that the claim was "inextricably intertwined" with their underlying claim for benefits, which was clearly barred from judicial review. *Id.* The Court recognized that, while raising a "supposed procedural" claim the plaintiffs, in fact, sought substantive relief—"the invalidation of the Secretary's current policy and a substantive declaration from her that the expenses of BCBR surgery are reimbursable under the Medicare Act." *Id.* And the Court was careful to emphasize that, "simply because a claim somehow can be construed as procedural," that does not make it cognizable in federal court.[2] *Id.*

Thus, at least in the context of the Medicare statute, Congress need not use any magic words

[2] The Supreme Court re-affirmed *Ringer* in *Shalala v. Illinois Council on Long Term Care, Inc.*, 529 U.S. 1 (2000), in which an association of nursing homes sought to challenge certain Medicare regulations on a variety of grounds, including that they violated the APA's notice and comment requirements. *See id.* at 7. The nursing homes argued that their claims could proceed under federal-question jurisdiction because they were "general" and "collateral" challenges rather than "fact-specific" or "noncollateral" claims. *Id.* at 13-14. The Supreme Court again rejected those purported distinctions, and held that *Ringer* was controlling. *See id.* at 13 ("Despite the urging of the Council and supporting *amici*, we cannot distinguish . . . *Ringer* from the case before us.").

to preclude purportedly procedural claims. Rather, even procedural claims are precluded when they raise a claim that falls within the plain text of a preclusion provision. "[T]o be true to the language of the statute, the inquiry in determining whether § 405(h) bars federal-question jurisdiction must be whether the claim 'arises under' the Act, not whether it lends itself to a 'substantive' rather than a 'procedural' label." *Id.* at 615.

Here, Plaintiff challenges the manner in which the Secretary promulgated the MFN Model, i.e. through an interim final rule rather than through advance notice and comment rulemaking. But this question is "inextricably intertwined" with the merits of a substantive challenge to the "selection" of the MFN Model, which § 1315a(d)(2) explicitly bars. Tellingly, as in *Heckler*, Plaintiff does not seek simply to force the agency to go through notice and comment rulemaking. Rather, it seeks invalidation of the MFN Rule in its entirety. Compl., Prayer for Relief. Because the supposed "procedural irregularities" in the "promulgation," are intertwined with the selection of the MFN Model, § 1315a(d)(2) strips the Court of subject matter jurisdiction to consider Plaintiff's procedural challenge.

B. Plaintiff's Substantive Claims are Without Merit.

i. CMS Properly Waived Notice and Comment for Good Cause Under the APA and the Medicare Statute.

Though agencies typically issue rules after notice and an opportunity to comment, an agency may forgo advance notice and comment "when the agency for good cause finds . . . that notice and public procedure thereon are impracticable, unnecessary, or contrary to public interest." 5 U.S.C. § 553(b)(B); 42 U.S.C. § 1395hh(b)(2)(C) (incorporating the Social Security Act's rulemaking requirement for the Medicare program). An agency may also make a rule immediately effective if it finds good cause to do so and explains that rationale in the rule. 5 U.S.C. § 553(d)(3). Courts generally construe the good-cause exception narrowly, but it still serves as "an important safety valve to be used where delay would do real harm." *United States v. Dean*, 604 F.3d 1275, 1279 (11th Cir. 2010). Though a court's "review of the agency's legal conclusion of good cause is *de novo*," the courts must "defer to

an agency's factual findings and expert judgments therefrom, unless such findings and judgments are arbitrary and capricious." *Sorenson Comm'n, Inc. v. FCC*, 755 F.3d 702, 706, 706 n.3 (D.C. Cir. 2014). And, even if this court concludes that a single one of CMS's justifications, "standing alone," would not constitute good cause, the court must consider whether the "combined effect" of that justification with others suffices. *Nat'l Women, Infants, & Children Grocers Ass'n v. Food & Nutrition Serv.*, 416 F. Supp. 2d 92, 107 (D.D.C. 2006).

CMS satisfied the requirements of the good-cause exception. It first noted the economic impact of out-of-pocket costs on Medicare Part B beneficiaries, finding that "increases in drug prices are causing beneficiaries to divert scarce resources to pharmaceutical treatments and away from other needs, or prompting them to skip doses of their medications, take less than the recommended doses, or abandon treatment altogether." 85 Fed. Reg. 76,249. CMS also found that, since "more than 25 million Medicare beneficiaries" live at or below 200 percent of the Federal Poverty Line, high drug prices for this population could result in "improper medication adherence or skipped treatment," which "can result in poor clinical outcomes for chronic disease management." *Id.* With the risk of severe illness from COVID-19 increasing "with age and the presence of chronic illnesses," combined with the inability to afford medications to manage chronic disease, CMS determined that "many older adults" are "at the highest risk levels." *Id.* Also considering the "historic levels of unemployment in the U.S." and "the increase in food prices" due to the pandemic, CMS concluded, "this population is in need of urgent relief from high drug prices in order to prevent stinting on care and alleviate general financial instability worsened by the COVID-19 pandemic." *Id.*

Considering all of this, CMS reasonably concluded that "there is good cause to waive the notice and comment requirements . . . because of the particularly acute need for affordable Medicare Part B drugs now, in the midst of the COVID-19 pandemic." *Id.* CMS also explained why urgent action was needed at this point in the pandemic, in particular: "[W]e are currently seeing a new surge

in COVID-19 cases that may lead to additional hardship and requires immediate action." *Id.* (citing Centers for Disease Control and Prevention. COVID–19 Forecasts: Cases. https://www.cdc.gov/coronavirus/2019-ncov/cases-updates/forecasts-cases.html). Accordingly, CMS determined that implementation of the MFN Model "will provide immediate relief to Medicare beneficiaries through reduced copays for MFN drugs due to lower drugs payments and no beneficiary cost-sharing on the alternative add-on payment." *Id.*

Plaintiff attempts to discount the urgent need to make medication more affordable for seniors in this time of unprecedented economic and health challenges, but this claim has no merit. For example, Plaintiff argues that CMS's delay in issuing the Rule precludes any finding of good cause to dispense with notice and comment. *See* Pl.'s Mot. 9–10. But this argument fails because it ignores CMS's explicit finding that the timing of the Rule was necessary because of a drastic change in the trajectory of the pandemic, not simply the existence of the pandemic itself, or the existence of high drug prices. *See* 85 Fed. Reg. 76,249 (discussing "new surge"). Thus, the timing of the Rule is distinguishable from that of the agency actions in *Natural Resources Defense Council v. National Highway Traffic Safety Admin. ("NHTSA")*, 894 F.3d 95, 114 (2d. Cir. 2018), where the court found unexplained delay when the "effective date of the [rule] was imminent only insofar as [the agency's] third finite delay was scheduled to elapse." Plaintiff similarly ignores CMS's factual finding that the "new surge in cases" requires "immediate action," 85 Fed. Reg. 76,249, in arguing that good cause is precluded because "the COVID-19 pandemic was declared a public health emergency" earlier this year. *Id.* The constantly changing landscape of an unprecedented global pandemic and the resulting compounding fiscal harm reasonably underlie the Secretary's decision. Plaintiff also conflates its delay argument

with the "impracticability" prong of the good-cause exception, which CMS does not invoke here. Rather, CMS invoked the good-cause exception in the public interest.[3]

Dispensing with notice and comment may be justified when "*providing* notice and comment would be contrary to the public interest." *Mack Trucks, Inc. v. EPA*, 682 F.3d 87, 95 (D.C. Cir. 2012). And, despite Plaintiff's conclusory statement that the public-interest prong can only be invoked when a "proposed rule's announcement would prompt 'manipulative tactics,'" its statement is directly contradicted by the very case it cites to support the proposition. *See* Pl.'s Mot. 11 (quoting *NHTSA*, 894 F.3d at 115). Indeed, in *NHTSA*, the court explained that manipulative tactics are an example of circumstances justifying invocation of the public-interest exception, but also expressly contemplated that "acute health or safety risk" may also justify the exception. 894 F.3d at 115. In evaluating the agency's invocation of good cause, the court must consider whether the "combined effect" of the agency's justifications suffice, even if the court concludes that a single one of CMS's justifications, "standing alone," would not constitute good cause. *Nat'l Women, Infants, & Children Grocers Ass'n*, 416 F. Supp. 2d at 107.

Here, the record supports CMS's invocation of good cause, particularly in light of the "new surge" of cases and its specific findings with about the financial and health burdens of the pandemic on seniors. *See* 85 Fed. Reg. 76,249; *cf. Nat. Res. Def. Council v. Abraham*, 355 F.3d 179, 205 (2d. Cir. 2004) (finding that "impending operation of a statute" cannot constitute a "threat to the *public* interest."). Thus, it is in the public interest to provide immediate relief for these seniors.[4] And, when actually considering the reasons stated by the agency, Plaintiff identifies no reason to doubt the

[3] Contrary to Plaintiff's argument, *see* Pl.'s Mot. 9, the APA does not require the agency to specify which component of the good cause exception applies. It requires only that the agency provide a "brief statement" in support of good cause. 5 U.S.C. § 553(b)(B).

[4] Plaintiff's reliance on *Chamber of Commerce of the United States v. DHS*, No. 20-cv-07331-JSW, 2020 WL 7043877 (N.D. Cal. Dec. 1, 2020), is misplaced. There, the court determined that there was a "significant mismatch of facts regarding the unemployment caused by the proliferation of the pandemic and the classes of workers impacted by the Rules," in holding that the agency's interim final rule was issued in violation of the APA." *Id.* at *10. Here, in contrast, the vulnerable population is directly impacted by the Rule.

Secretary's finding of good cause. *Cf. Capitol Area Immigrants' Rights Coal. v. Trump*, 2020 WL 3542481 at *15 (D.D.C. June 30, 2020) ("declining to defer to an agency's predictive judgment without adequate record or explanation" when judgment was based on one newspaper article).

ii. CMS Promulgated the MFN Model Rule Within its Statutory Authority.

Congress authorized the Secretary, through the Center, to create bold new innovative models designed to test the reduction of program expenditures for Medicare and Medicaid while preserving or enhancing the quality of care for beneficiaries. 42 U.S.C. § 1315a(a)(1). The MFN Model is one such innovative model. It charts a seven-year, nationwide model to test the reduction of unsustainable expenditures paid by the government and beneficiaries for 50 Medicare Part B drugs by tying the Medicare payment allowance for these drugs to prices paid by our international counterparts.

To facilitate innovation, Congress established two distinct phases of model testing: (1) an initial model test (Phase I); and (2) an optional model expansion (Phase II). *See* 42 U.S.C. § 1315a(b) (Phase I); *id.* § 1315a(c) (Phase II). During Phase I, the Secretary "*may* elect to limit testing of a model to [a] certain geographic area." *Id.* § 1315a(a)(5) (emphasis added). Instead of placing inflexible scope or geographic limits on a Phase I model, Congress supplied different metrics. To comply with the statute, a Phase I model need only be (1) an innovative payment and service delivery model; (2) addressing a defined population for which there are deficits in care leading to poor clinical outcomes or potentially avoidable expenditures; and (3) capable of evaluation. *Id.* § 1315a(b).

This court's review of the Secretary's compliance with and interpretation of § 1315a is governed by the *Chevron* framework. *See Chevron, U.S.A, Inc. v. Nat. Res. Def. Council*, 467 U.S. 837, 842–43 (1984). To the extent that the court determines that the plain meaning of the statute is ambiguous, it must accord deference to the Secretary's interpretation of the statute, because the agency's interpretation of the statute is "based on a permissible construction of the statute." *City of Arlington v. FCC*, 569 U.S. 290, 296 (2013) (quoting *Chevron*, 467 U.S. at 843).

Plaintiff presents several ways in which it believes the Rule exceeds CMS's statutory authority, but none are persuasive. Plaintiff first contends that the Rule is not a "model" addressing a "defined population" with specific "deficits in care." These terms are undefined in the statute, but, as just

explained, the statute describes the characteristics of a qualifying model test. 42 U.S.C. § 1315a(b). The MFN Model complies with each of those criteria. It is a payment model directed at the defined population of Medicare Part B beneficiaries using a covered drug, for which there have been skyrocketing costs that the Secretary determined should be addressed. In the "Defined Population" section of the Rule, CMS states: "the defined population for the MFN Model will be Medicare FFS [fee-for-service] beneficiaries who receive an MFN Model drug from an MFN participant where payment for such drug is allowed under the MFN Model." 85 Fed. Reg. 76,183. As the excerpted language makes clear, the MFN Model addresses a population that is narrower than "every Medicare beneficiary." Pl.'s Mot. 13.[5] For example, the defined population included in the Model does not include Medicare FFS beneficiaries who receive drugs that are not one of the 50 tested in the Model; nor does it apply to Medicare beneficiaries who receive services through a managed care plan (as opposed to fee-for-service). The Rule also sets forth "potentially avoidable expenditures," with estimated cost savings predicted to amount to $85.5 billion in Medicare Part B spending, and $28.5 billion for Medicare beneficiaries. 85 Fed. Reg. 76,181. Of course, a reduction in Medicare Part B spending will result in a reduction in Medicare expenditures more generally, which is entirely consistent with Congress's requirement that "[t]he Secretary *shall* focus on models *expected to reduce program costs*." 42 U.S.C. § 1315a(b)(2)(A) (emphasis added). And though the MFN Model may differ from some of the exemplars specifically enumerated in § 1315a, Pl.'s Mot. 13, Congress provided that the models selected "may include, but are not limited to" the models included within the statute. 42 U.S.C. § 1315a(b)(2)(A). What is more, Congress specifically contemplated models that could be implemented on a nationwide scale, such as "[p]romoting broad payment and practice reform in primary care." *Id.* § 1315a(b)(2)(B)(i).

Plaintiff contends that the model cannot be evaluated because there is no independent

[5] Plaintiff protests that a "defined population" cannot be defined as "whatever group the MFN Rule benefits" because that would be "circular." Pl.'s Mot. 13, n.14. But Plaintiff gets it entirely backward. The Secretary is statutorily required to identify a "model" which "addresses a defined population for which there are deficits in care leading to poor clinical outcomes *or* potentially avoidable expenditures." 42 U.S.C. § 1315a(b)(2)(A) (emphasis added). Consistent with the statute, the defined population for the MFN Model will be the group for whom the Secretary has determined there are potentially avoidable expenditures.

comparison group to establish a counterfactual. Pl.'s Mot. 13–14; *see also* 42 U.S.C. § 1315a(b)(4) (listing evaluation requirements). But this contention lacks merit. Despite the absence of a counterfactual comparison group, the Rule contains a detailed discussion about the method CMS will employ to evaluate the MFN Model. 85 Fed. Reg. 76,232–34. An independent comparison group is not statutorily required for an evaluation of a Phase I model, and CMS's approach will still result in an evaluation that meets the statutory requirements.

Plaintiff next asserts that the MFN Model cannot be a model because it is not a precursor to congressional legislation. Pl.'s Mot. 14. This too lacks merit. Congress and CMS are not acting in spheres of mutual exclusivity: The Center is designed to be a laboratory for testing innovative payment and service models that Congress may later improve, develop, or build upon. *See* 42 U.S.C. § 1315a(g). The MFN Model is no exception. If the Model is successful, Congress could codify a version the model that includes all drugs, other parts of the Medicare program, or a permanent duration. Thus, the Model, if successful, could precede future legislative action.[6]

Plaintiff finally argues that § 1315a does not authorize "transformative" regulations with significant economic effects. Pl.'s Mot. 14–15. But the cases on which Plaintiff relies were based on an "implicit" delegation of authority to an agency. *Util. Air Regul. Grp. v. EPA*, 573 U.S. 302, 324 (2014); *King v. Burwell*, 576 U.S. 473, 486 (2015). There is nothing implicit about Congress's delegation of authority to CMS in § 1315a. Congress anticipated that models may test broad changes in the Medicare system on a nationwide scale. *See, e.g.*, 42 U.S.C. § 1315a(b)(2)(B)(i) (explicitly authorizing a model "[p]romoting broad payment and practice reform in primary care"). Congress is well aware that broad payment and service delivery reform in the Medicare system—as the Federal Government is the largest purchaser of drugs in the world—will almost inevitably affect questions of economic significance. Though Plaintiff frames its argument as one involving an "implicit" delegation, the

[6] Plaintiff also contends that the Rule cannot stand because it relies on a provision of the Affordable Care Act, and the Administration has taken the position while litigating at the Supreme Court that the ACA is invalid in its entirety. Pl.'s Mot. 12. But statutes are declared invalid by courts, not positions taken in parties' legal briefs. Moreover, the Executive Branch continues to operate under the Affordable Care Act while challenges to it are being litigated. *Cf. United States v. Windsor*, 570 U.S. 744, 756 (2013) (Executive Branch practice to enforce challenged statutory provision pending definitive resolution of provision's validity by the courts, while declining to defend provision in court).

question is actually whether Congress's *explicit* delegation properly delegated legislative authority to the Center to create innovative models. Congress did so. Its delegation to CMS is not so standardless, or so lacking in any guiding "intelligible principles," as to provide no guidance whatsoever. *Gundy v. United States*, 139 S. Ct. 2116, 2129 (2019) (plurality op.), *reh'g denied*, 140 S. Ct. 579 (2019). Section 1315a provides specific benchmarks and ample standards to guide the Secretary's selection and testing of models.

iii. The Rule is Within the Bounds of Reasoned Decisionmaking.

The APA requires a reviewing court to "hold unlawful and set aside" arbitrary or capricious agency action. 5 U.S.C. § 706(2)(A). "The scope of review" under that standard "is narrow and a court is not to substitute its judgment for that of the agency." *Motor Vehicles Mfrs. Ass'n of U.S., Inc. v. State Farm Mut. Auto. Ins. Co.,* 463 U.S. 29, 43 (1983). The ultimate question is whether the agency acted "within the bounds of reasoned decisionmaking." *Balt. Gas & Elec. Co. v. Nat. Res. Def. Council Inc.*, 462 U.S. 87, 105 (1983). "A court will not 'lightly' reach [the] conclusion" that an agency failed to consider an important aspect of the problem. *State v. Dep't of Justice*, 951 F.3d 84, 122 (2d Cir. 2020) (citation omitted). The reviewing court may not "second-guess[] the [agency's] weighing of risks and benefits and penaliz[e] [it] for departing from the . . . inferences and assumptions" of others. *Dep't of Commerce v. New York*, 139 S. Ct. 2551, 2571 (2019), *remanded*, 2019 WL 3213840 (S.D.N.Y. July 16, 2019).

Plaintiff contends that CMS failed to consider a number of issues: the Rule would adversely affect innovation and public health because drug manufacturers would see less money for investment; price controls would "lead to shortages"; drug manufacturers' monetary-reliance interests; and finally, some drug manufacturers have no control over prices outside the U.S. for particular drugs. Pl.'s Mot. 15–16. The Rule, which spans more than 80 pages in the Federal Register, addressed important issues and falls squarely within the bounds of reasoned decisionmaking. CMS explicitly acknowledged the potential pharmaceutical market disruption and adopted a phased approach to address this concern, while also testing ways to provide the benefits of savings for beneficiaries and taxpayers that are central

to the Rule. *See* 85 Fed. Reg. 76,204, 76,205, 76,213.[7] The Rule likewise acknowledges that businesses may be required to "adjust[] purchasing arrangements" or "substantially chang[e] their pricing models." *Id.* at 76,244. But CMS determined that this potential impact was justified by the potential benefits of the Rule. The Rule also tests ways to address the potential for shortages and a solution that would reimburse for a drug based on the non-MFN Model payment amount if the FDA determines it is "in shortage." *Id.* at 76,215. Moreover, CMS retains the ability to grant hardship exemptions, *id.* at 76,222, as well as the authority to cease or modify a model if it is not achieving the goals of the statute. 42 U.S.C. § 1315a(b)(3)(B). The APA does not require an agency to "conduct a formal cost-benefit analysis in which each advantage and disadvantage is assigned a monetary value." *Michigan v. EPA*, 576 U.S. 743, 759 (2015). Nor are agencies required to exhaustively consider any possible problem that may arise. Plaintiff has offered no authority for its position that an agency decision is arbitrary and capricious unless it expressly and exhaustively addresses every possible counterargument.[8] CMS satisfied its obligation to consider important aspects of the problem and engage in reasoned decisionmaking.

iv. Section 1315a Satisfies the Constitutional Requirement of Presentment.

Article I of the Constitution includes the Presentment Clause, which the Supreme Court has interpreted to bar "unilateral Presidential action that either repeals or amends parts of duly enacted statutes," and which wholly prevents legislation "from having legal force or effect." *Clinton v. City of New York*, 524 U.S. 417, 438–39 (1998); U.S. Const., art. I, § 7, cl. 2. Plaintiff contends 42 U.S.C. § 1315a violates the Constitution's presentment requirement because the waiver provision empowers the Secretary to repeal essential portions of the Medicare Act. Pl.'s Mot. 17–18. But Plaintiff's premise

[7] *See* 85 Fed. Reg. 76,204 ("We will use a phase-in approach that will blend the MFN Price with the applicable ASP to allow MFN participants time to adjust to the model payment amounts and processes."), and *id.* at 76,205 ("We believe that a phase-in approach during the initial years of the model will enable MFN participants and the markets to adjust to the model's payment methodology, while enabling CMS to test the full phase-in of the MFN.")

[8] Plaintiff also contends that the Rule is arbitrary and capricious because the Secretary promulgated the Rule as retaliation for the pharmaceutical industry's failure to support the President's reelection. Pl.'s Mot. 16–17 (citing *Dep't of Commerce v. New York*, 139 S. Ct. 2551, 2575 (2019)). From this, Plaintiff asserts: "[i]t is plainly arbitrary and capricious to either forgo notice and comment or issue a substantive rule for such reasons, while claiming an alternative basis for the actions." *Id.* Defendants debunk the asserted retaliation claim. *See* page 24, *supra*. And, in any event, the relied-upon authority does not support Plaintiff's claim about arbitrary-and-capricious action because the Supreme Court did not base its decision on retaliation or animus. *Dep't of Commerce*, 139 S. Ct. at 2575.

is fundamentally incorrect. Even after the effective date of the MFN Model, the provisions to which Plaintiff refers will continue to maintain "legal force and effect." *Clinton*, 524 U.S. at 439.

To support an argument that the Secretary acted unilaterally to scuttle the policy judgment of Congress, Plaintiff relies on *Clinton v. City of New York*. In that case, however, the Court invalidated the Line Item Veto Act, which gave the President veto authority to "cancel in whole" certain appropriated spending items enacted by Congress a mere days earlier. *Id.* at 436. The President's "cancellation" prevented those items "from having legal force or effect," and thus in "*both* legal and practical effect, the President ha[d] amended two Acts of Congress by repealing a portion of each." *Id.* at 438 (emphasis added); *see also id.* at 447, 444 (holding it improper to give the President "unilateral power to change the text of duly enacted statutes" and "within five days" to "reject [] the policy judgment made by Congress and rely[] on his own policy judgment.").

Section 1315a(d)(1) differs drastically from the Line Item Veto Act and does not amount to a repeal of a statute. It is undisputed that 1315a—the statutory authority for the Rule—itself passed both houses of Congress, and was signed into law by the President of the United States. It is *that* duly enacted statute—not the Rule—which expresses the policy judgment of Congress that was carried out by CMS. This congressional policy judgment includes the creation of the Center to "test innovative payment and service delivery models" with the goal of "reduc[ing] program expenditures" while maintaining, or even improving, a high standard for "quality of care." 42 U.S.C. § 1315a(a)(1). To ensure maximum flexibility in this endeavor, Congress included a waiver provision, which explicitly authorizes the Secretary to waive otherwise applicable requirements under the Medicare statute. *Id.* § 1315a(d)(1). One such waiveable provision includes the Medicare Part B drug reimbursement provision. *See Id.* § 1395w-3a.

Plaintiff essentially contends that because the Rule will change the market-based reimbursement system for *some* Medicare Part B drugs, the Rule has the "legal and practical effect" of repealing § 1395w-3a. Pl.'s Mot. 17–18. But § 1395w-3a undeniably retains its "legal force and effect" after the MFN Model goes into effect, and thus cannot be said to be effectively repealed: the Medicare Part B reimbursement rates described in the statute will continue to be in effect for more than 500

drugs not covered by the Rule.[9] And in 2021, payment for drugs that are part of the MFN Model will continue to be reimbursed based on 75% of the market-based payment rates provided for in § 1395w-3a.[10]

Plaintiff does not cite any authority in which the Court has extended *Clinton* to include a "waiver" provision of the sort found in § 1315a, and Plaintiff identifies no other basis to conclude that the waiver provision in § 1315a violates the Constitution. *See Republic of Iraq v. Beaty*, 556 U.S. 848, 861 (2009) ("The [statutory] proviso *expressly* allow[ing] the President to render certain statutes inapplicable . . . . did not repeal anything, but merely granted the President authority to waive the application of particular statutes to a single foreign nation."). The U.S. Code and the Medicare statute are replete with examples of waivers, and such waivers are routinely upheld.[11] In short, these statutory waivers are not uncommon, and they are certainly not unconstitutional.

And though Plaintiff makes much out of the fact that the Rule changes the reimbursement system for the purposes of testing the MFN Model, *Congress*—not the Executive—made that policy judgment. Congress unmistakably expressed its policy judgment that, in order to foster innovation and flexibility in payment- and service-delivery models, waivers of particular requirements of the Medicare statute governing traditional modes of payment may be in order, including those pertaining to Part B drug reimbursement rates. The Secretary did not act unilaterally, to substitute his judgment about Medicare pricing or to repeal Congress's reimbursement scheme. He invoked a valid statutory provision to accomplish ends that § 1315a explicitly permits, and in so doing, *executed* rather than rejected the will of Congress. *Clinton*, 524 U.S. at 444. That does not violate the Presentment Clause.

v. The Rule Does Not Violate the First Amendment.

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[9] *See* https://www.cms.gov/index.php/medicare/medicare-part-b-drug-average-sales-price/2021-asp-drug-pricing-files (most recent Part B pricing list). The percentage may be different in certain narrowly prescribed cases as described by the Rule. *See* 42 C.F.R. § 513.210(d)(3).

[10] Defendants' assert that § 1315a's waiver cannot be interpreted as a repeal of the Medicare statute. But even if the court were to interpret it that way, Plaintiff's argument seems to indicate that Congress is without authority to enact laws that may, at times, override prior laws. But there is simply no requirement—constitutional or otherwise—that Congress take some clerical action to formally amend or repeal an older law (or regulation) before enacting a new law. *See, e.g.*, *Hellon & Assocs., Inc. v. Phoenix Resort Corp.*, 958 F.2d 295, 297 (9th Cir. 1992).

[11] *See Beaty*, 556 U.S. at 861; *accord Defs. of Wildlife v. Chertoff*, 527 F. Supp. 2d 119, 125 & n.5 (D.D.C. 2007) (collecting some of the "myriad examples of waiver provisions in federal statutes"); *see also* 42 U.S.C. §§ 1315(a)(1), 1395jjj(f), 1395b-1, 1395cc-3(e), 1395cc-4(d), 1395cc-5(e)(6), 1395cc-6(i) (Medicare-specific waivers).

Plaintiff argues that the "President's own words demonstrate that the MFN Rule was issued as retaliation for political speech" in violation of the First Amendment. Pl.'s Mot. 18–19. Aside from quoting the President's remarks and the excerpted conclusory statement, Plaintiff makes no argument and points to no authorities to support its assertion that the President's remarks had any effect on the statutorily designated decisionmaker—the Secretary of Health and Human Services. 42 U.S.C. §§ 1302, 1395hh; *see Dorsett v. Cty. of Nassau*, 732 F.3d 157, 160 (2d Cir. 2013) (retaliatory action must be motivated or caused by protected speech). The Secretary alone is responsible for promulgating the Rule, and Plaintiff has not alleged any nexus between the President's statements and the promulgation of the Rule.

Plaintiff's brief contains an additional scattershot of vague and undeveloped arguments buried in footnotes, including that the Rule: "violates the Foreign Commerce Clause," Pl.'s Mot. 19 n.18; "constitutes a taking without just compensation," *id.*; and violates the non-delegation doctrine, *id.* at 18 n.16. These conclusory references to substantive constitutional claims are insufficient to support a claim, "inadequately raised," and "waived." *Fin. Guar. Ins. Co. v. Putnam Advisory Co., LLC*, 12-cv-7372 (AT), 2020 WL 264146, at *2 (S.D.N.Y. Jan. 17, 2020) (citation omitted).

II. PLAINTIFF FAILED TO ESTABLISH IRREPARABLE HARM.

Merits aside, Plaintiff is not entitled to a temporary restraining order because it has not demonstrated that it is likely to suffer irreparable harm in the absence of preliminary relief. "A showing of irreparable harm is 'the single most important prerequisite for the issuance of a preliminary injunction.'" *Faiveley Transp. Malmo AB v. Wabtec Corp.*, 559 F.3d 110, 118 (2d Cir. 2009) (quoting *Rodriguez v. DeBuono*, 175 F.3d 227, 234 (2d Cir. 1999)). A plaintiff seeking an injunction must "demonstrate that irreparable injury is *likely* in the absence of an injunction." *Winter*, 555 U.S. at 22. "Likelihood sets, of course, a higher standard than 'possibility.'" *Impax Media, Inc. v. Ne. Advert. Corp.*, 17-cv-8272, 2018 WL 358284, at *4 (S.D.N.Y. Jan. 10, 2018) (quoting *Johnson Controls, Inc. v. A.P.T. Critical Sys., Inc.*, 323 F. Supp. 2d 525, 532 (S.D.N.Y. 2004)). Although the Second Circuit has found that irreparable injury may occur where a party is unable to recover economic losses from the

Government (*see, e.g.*, *United States v. New York*, 708 F.2d 92, 93-94 (2d Cir. 1983)), a plaintiff seeking a preliminary injunction still must "'demonstrate that absent a preliminary injunction they will suffer an injury that is neither remote nor speculative, but actual and imminent.'" *Faiveley Transp.*, 559 F.3d at 118 (quoting *Grand River Enter. Six Nations, Ltd. v. Pryor*, 481 F.3d 60, 66 (2d Cir. 2007)). Plaintiff has not done so here.

Although Plaintiff claims that the Rule will have an "extraordinary" effect on its revenues, that conclusory assertion is insufficient to establish irreparable harm. First, Plaintiff does not explain how it calculated its anticipated losses. *See generally* Declaration of Richard O'Neal, ECF No. 13 ("O'Neal Decl."). That alone casts doubt on Plaintiff's claimed harms. More importantly, however, Plaintiff relies on its anticipated losses during the entirety of 2021 (and in the subsequent years of the MFN Model), "and therefore gives the Court little insight into the magnitude of its loss during the pendency of this case." *CoverDyn v. Moniz*, 68 F. Supp. 3d 34, 47 (D.D.C. 2014). The test for a TRO or preliminary injunction is not simply whether a plaintiff will be harmed, but whether "[it] is likely to suffer irreparable harm *in the absence of preliminary relief*." *Citizens United v. Schneiderman*, 115 F. Supp. 3d 457, 462 (S.D.N.Y. July 27, 2015) (quoting *N.Y. Progress & Prot. PAC v. Walsh*, 733 F.3d 483, 486 (2d Cir. 2013)) (emphasis added). Furthermore, the "extraordinary" losses that Plaintiff anticipates amount to a sliver of Regeneron's total stated revenue of $7.86 billion in 2019.[12] These purported losses "do not rise to the level of irreparable harm." *ConverDyn*, 68 F. Supp. 3d at 48; *see also id.* at 49 ("[A] party seeking injunctive relief due to the inability to recover economic losses must nonetheless demonstrate that its harm will be sufficiently great to warrant a preliminary injunction"); *Cal Pharmacists Ass'n v. Maxwell-Jolly* (*"Cal. II"*), 596 F.3d 1098, 1113–14 (9th Cir. 2010), *vacated & remanded sub nom*, *Douglas v. Indep. Living Ctr. of S. Cal., Inc.*, 565 U.S. 606 (2012) (Medicaid providers must show that they "will lose considerable revenue through the reduction in payments that they will be unable to recover" due to sovereign immunity); *Otsuka Pharm. Co. v. Burwell*, 2015 WL 1962240, at *11 (D. Md. Apr. 29, 2015) ("That [Plaintiff] is unable to recover monetary damages from [Defendants] does not . . .

[12] *See* Regeneron Pharmaceuticals, Inc., Annual Report (Form 10-K) (Feb. 7, 2020) at 63 (reporting revenue of $7,863,400,000 for 2019). "SEC forms such as . . . Form 10-K are matters of public record and may be subject to judicial notice." *Wynn v. Chanos*, 75 F. Supp. 3d 1228, 1235 (N.D. Cal. 2014).

automatically make [it]s harm irreparable."); *Ariz. Hosp. & Healthcare Ass'n v. Betlach*, 865 F. Supp. 2d 984, 1000 (D. Ariz. 2012).

Plaintiff's claims of competitive and reputational injury are similarly unavailing. Plaintiff theorizes that doctors will switch their patients to new medications, and that "at least some of those patients" are unlikely to switch back even if the Rule is eventually enjoined. Pl.'s Mot. 23. In support of that claim, Plaintiff notes that it "has already begun receiving questions from doctors and organizations that advocate on behalf of doctors" about "the looming need to switch patients" to new medications. O'Neal Decl. ¶ 24. But it offers no explanation why patients would not switch back if the Rule were eventually enjoined. Similarly, Plaintiff insists that renegotiating its contracts with providers and suppliers will lead to "reputational and competitive injury resulting from Regeneron's need to renegotiate contracts." *Id.* ¶ 29. But corporations renegotiate contracts all the time, and it is hard to imagine that renegotiating contracts to *lower* the price of a product will cause reputational harm. At minimum, Plaintiff must provide more than its own say-so to establish that this will lead to irreparable harm. "In failing to supply evidence of the loss of reputation or good will beyond [its] own conclusory averments, Plaintiff has not made a sufficient showing that irreparable harm is likely at this point in this action." *Rush v. Hillside Buffalo, LLC*, 314 F. Supp. 3d 477, 486 (W.D.N.Y. 2018).

Finally, Plaintiff claims that it will "fall behind in innovation to competitors not subject to the MFN Rule." Pl.'s Mot. 23. Once again, Plaintiff does not explain how these harms will accrue immediately after the Rule goes into effect. Plaintiff contends that it will need to "reduce [its] investment in research and development," but it offers no evidence that it must make immediate changes to its research and development budget. O'Neal Decl. ¶ 35.

Plaintiff's alleged procedural injury does not constitute *irreparable* harm. As an initial matter, the Secretary had good cause to forgo advance notice and comment procedures. *See* pages 14–17, *supra*. Accordingly, Plaintiff has not demonstrated any deprivation of a procedural right. Moreover, even if Plaintiff *did* have a pre-promulgation right to comment on the Rule, procedural injury alone would not constitute the type of irreparable harm necessary to sustain a temporary restraining order. After all, if Plaintiff ultimately prevails on its notice-and-comment claim, any procedural harm would

be ameliorated through the ordinary litigation process. Thus, to justify the issuance of preliminary relief, Plaintiff must show that "unless the [Rule] is enjoined," it is "likely to experience not just *some* injury, but *irreparable harm* that cannot be cured by ultimate success on the merits in this case." *Northern Mariana Islands v. United States*, 686 F. Supp. 2d 7, 17 (D.D.C. 2009) (emphasis added). Plaintiff has not made that showing here.

Nor does Plaintiff show an irreparable injury by alleging constitutional claims. Because Plaintiff is unlikely to succeed on the merits of those claims (*see* pages 22–24), *supra*, it cannot rely on them as the basis for finding irreparable harm. Setting the merits aside, Plaintiff has not alleged the type of constitutional injuries that merit a finding of irreparable injury. Specifically, Plaintiff contends that the Rule violates the separation of powers and the First Amendment. But "while a violation of constitutional rights can constitute *per se* irreparable harm, . . . *per se* irreparable harm is caused only by violations of 'personal' constitutional rights . . . to be distinguished from provisions of the Constitution that serve 'structural' purposes, like the Supremacy Clause," and the latter do not establish *per se* irreparable harm. *N.Y. State Rest. Ass'n v. N.Y.C. Bd. of Health*, 545 F. Supp. 2d 363, 367 (S.D.N.Y. 2008) (quoting *Equal Emp. Opportunity Comm'n v. Local 638*, 1995 WL 355589, at *5 (S.D.N.Y. 1995)), *rev'd on other grounds*, 556 F.3d 114 (2d Cir. 2009); *Pub. Serv. Co. of N.H. v. Town of W. Newbury*, 835 F.2d 380, 382 (1st Cir. 1987); *Am. Petroleum Inst. v. Jorling*, 710 F. Supp. 421, 431 (N.D.N.Y. 1989). And "[w]here, as here, 'a plaintiff alleges injury from a rule or regulation that may only potentially affect speech,' it must 'articulate a specific present objective harm or a threat of specific future harm.'" *Citizens United*, 115 F. Supp. 3d at 473 (quoting *Bronx Household of Faith v. Bd. of Educ. of City of New York*, 331 F.3d 342, 350 (2d Cir. 2003). Plaintiff ordinarily satisfies this requirement by "establishing an actual chilling effect." *Bronx Household of Faith v. Bd. of Educ. of City of New York*, 331 F.3d 342, 349 (2d Cir. 2003). Plaintiff has not even alleged a possible chilling effect, let alone *established* an *actual* one.

III. THE BALANCE OF THE EQUITIES AND THE PUBLIC INTEREST WEIGH AGAINST THE REQUESTED INJUNCTION.

The balance of hardships and the public interest weigh against issuing an injunction here. Where the government is a party, these two inquiries merge. *Nken*, 556 U.S. at 435. "[T]here is

inherent harm to an agency in preventing it from enforcing regulations that Congress found it in the public interest to direct that agency to develop." *Cornish v. Dudas*, 540 F. Supp. 2d 61, 65 (D.D.C. 2008), *aff'd*, 330 F. App'x 919 (Fed. Cir. 2009); *Seaside Civic League, Inc. v. U.S. Dep't of Housing & Urban Dev.*, 2014 WL 2192052, at *3 (N.D. Cal. 2014). As the Rule explains, "[h]igh drug prices in the U.S. have serious economic and health consequences for beneficiaries in need of treatment." 85 Fed. Reg. 76,249. It is in the public interest for the Government to take steps to reduce those burdens—particularly where, as here, the Secretary has determined that "[t]he COVID-19 pandemic has rapidly exacerbated these problems" (*id.*), and the Rule is urgently needed to mitigate those consequences. *See* pages 14–17, *supra*.

IV. ANY INJUNCTIVE RELIEF SHOULD BE LIMITED TO THE PLAINTIFF.

At a minimum, any temporary restraining order or preliminary injunction should be no broader than necessary to provide Plaintiff with relief. Plaintiff appears to seek nationwide relief, notwithstanding the fact that nationwide injunctions are "legally and historically dubious." *Trump v. Hawaii*, 138 S. Ct. 2392, 2492 (2018) (Thomas, J., concurring), *remanded*, 898 F.3d 1266 (9th Cir. 2018). "A plaintiff's remedy must be tailored to redress *the plaintiff's* particular injury." *Gill v. Whitford*, 138 S. Ct. 1916, 1921, 1933–34 (2018) (quoting *Califano v. Yamasaki*, 442 U.S. 682, 702 (1979)) (emphasis added); *see also Madsen v. Women's Health Ctr., Inc.*, 512 U.S. 753, 765 (1994) (explaining that an injunction should "be no more burdensome to the defendant than necessary to provide complete relief to the plaintiffs"). But Plaintiff has offered no explanation why a nationwide injunction is necessary to redress its alleged injuries.

Nationwide relief would be particularly harmful here given that other plaintiffs have filed lawsuits in district courts in California, Maryland, and the District of Columbia challenging the Rule. *Biotechnology Innovation Org. v. Azar*, No. 3:20-cv-08603 (N.D. Cal.); *Ass'n of Cmty. Cancer Ctrs. v. Azar*, No. 1:20-cv-3531 (D. Md.); *Community Oncology Alliance, Inc. v. Azar*, No. 1:20-cv-03604 (D.D.C.). If the government prevails in these other jurisdictions, it would render those victories meaningless as a practical matter. It would also preclude appellate courts from testing Plaintiff's factual assertions against the MFN Rule's operation in other jurisdictions. *See Dep't of Homeland Security v. New York*, 140

S. Ct. 599, 600 (2020) (Mem.) (Gorsuch, J., concurring) ("The traditional system of lower courts issuing interlocutory relief limited to the parties at hand . . . . encourages multiple judges and multiple circuits to weigh in only after careful deliberation, a process that permits the airing of competing views that aids this Court's own decisionmaking process."), *modification denied*, 140 S. Ct. 2709 (2020); *cf. California v. Azar*, 911 F.3d 558, 583 (9th Cir. 2018) (recognizing that "nationwide injunctive relief may be inappropriate where a regulatory challenge involves important or difficult questions of law, which might benefit from development in different factual contexts and in multiple decisions by the various courts of appeals") (quoting *L.A. Haven Hospice, Inc. v. Sebelius*, 638 F.3d 644, 664 (9th Cir. 2011)).

CONCLUSION

For the foregoing reasons, Plaintiff's motion for a temporary restraining order and preliminary injunctive relief should be denied.

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Respectfully submitted,

JEFFREY BOSSERT CLARK
Acting Assistant Attorney General
Civil Division

MICHELLE R. BENNETT
Assistant Branch Director

s/*Lisa N. Newman*
LISA N. NEWMAN
RACHAEL L. WESTMORELAND
ALEXANDRA R. SASLAW
Trial Attorneys
United States Department of Justice
Civil Division, Federal Programs Branch
P.O. Box 883
Washington, DC 20044
Phone: (202) 353-5882
Lisa.n.newman@usdoj.gov

Attorneys for Defendants